The European Agency for the Evaluation of Medicinal Products
Pre-authorisation Evaluation of Medicines for Human Use

London, 17 October 2003
CPMP/2811/03

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP) SUMMARY INFORMATION ON A REFERRAL OPINION FOLLOWING AN ARBITRATION PURSANT TO ARTICLE 29 OF DIRECTIVE 2001/83/EC, FOR

ISOTRETINOIN / LURANTAL / TRIVANE / REXIDAL / SCHERITONIN (See Annex I)

International Non-Proprietary Name (INN): Isotretinoin

BACKGROUND INFORMATION

Isotretinoin (13-cis-retinoic acid) is a retinoid compound and a derivative of vitamin A. Isotretinoin is used for the systemic treatment of acne. Like all retinoids, isotretinoin is teratogen and is contraindicated during pregnancy to avoid congenital defects.

A marketing authorisation for Isotretinoin was granted to Schering Health Care Ltd in UK, on 16 August 2001. The dossier was submitted as a so called "generic application", as essentially similar to Roaccutane first authorised in EU in 1983. Applications for mutual recognition of Isotretinoin were submitted to Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal and Spain. The Mutual Recognition Procedure started on 4 February 2002.

On 3 May 2002, France presented to the EMEA a referral under Article 29 of Directive 2001/83/EC. The referral by France mainly related to the pregnancy prevention measures proposed for this generic product as reflected in the summary of product characteristics of the mutual recognition procedure.

The referral procedure started on 30 May 2002.

During its April 2003 meeting, the CPMP, in the light of the overall submitted data and the scientific discussion within the Committee, was of the opinion that a marketing authorisation should be granted provided amendment to the summary of product characteristics. In particular, isotretinoin (oral) should only be prescribed to women of childbearing potential under strict pregnancy prevention measures supported by a Pregnancy Prevention Programme (see annex III, amended summary of product characteristics). A positive opinion was therefore adopted on 25 April 2003.

The scientific conclusions and the grounds for the amendment of the Summary of Product Characteristics are set out in Annex II, together with the amended Summary of Product Characteristics in the Annex III.

The final opinion was converted into a Decision by the European Commission on 17 October 2003.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 13
E-mail: mail@emea.eu.int http://www.emea.eu.int